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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,412	KRANIAS ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-14,16,17 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,18,19 and 21* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/2006 has been entered.

2. Currently, claims 1-17 and newly added claims 18-21 are pending in the instant application. Claims 1-14, 16, 17, and 20 are withdrawn from consideration as being drawn to non elected inventions. Claims 15, 18, 19 and 21 are currently under examination. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. This action is Non-Final.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 15, 18, 19, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "an isolated nucleic acid comprising a phospholamban polymorphism *comprising* a G to T mutation at position 116 of a nucleic acid having *a* sequence of nucleic acids set forth as SEQ ID NO: 1". This recitation is confusing for the following reasons. Firstly, it is unclear if the claimed nucleic acid has a G or a T at a position corresponding to position 116 of SEQ ID NO: 1. The recitation of "G to T" appears to imply that a T is present at position SEQ ID NO: 1 instead of a G. However a T is already present at position 116 of SEQ ID NO: 1. A G is present at position 116 of SEQ ID NO: 7. It is not clear therefore if applicants intended to encompass a nucleic acid molecule comprising SEQ ID NO: 1, (the claimed recitation does now encompass this recitation), or if the claim was meant to be limited to "T" at position 116. If the latter is the case, claim 21 would not necessarily further limit claim 15.

In claim 1, the recitation of "comprising a phospholamban polymorphism comprising... of *a* nucleic acid sequence having *a* sequence of nucleic acids set forth as SEQ ID NO:1" is indefinite because it is unclear whether the claim is limited to a nucleic acid sequence which comprises only a "portion" of SEQ ID NO: 1, but can have any additional mutations relative to SEQ ID NO: 1, or if it is encompasses a nucleic acid comprising SEQ ID NO: 1 with a G or a T at position 116, or a fragment thereof, wherein no other mutations relative to SEQ ID NO: 1 are encompassed, or whether it is limited to a nucleic acid comprising SEQ ID NO: 1 with a G or a T. It is noted that while the third option may have been intended, it is contraverted by the term "fragment" in dependent claim 18. Due to the confusing claim language in claim 15, as well as the dependencies of claim 18, 19, and 21, the examiner is unable to assess whether claim 1 is limited to a G or a T at position 116, and what the metes and bounds of the specific molecule being claimed is. Further, the recitation of "comprises a phospholamban polymorphism" is also

confusing. The term "polymorphism" is normally used to denote a nucleotide change, therefore, a nucleic acid which comprises a "phospholamban polymorphism" only limits the claim to any nucleic acid which has a G or a T.

Claim 19 is indefinite in the recitation of "L39StopCodon" as the number used has no reference. In other words, the number is arbitrary without a reference with which to compare it to. The claim is now dependent ultimately from claim 15. In the instant case, the claim broadly reads on any phospholamban sequences from any species, including mutants, variants, and homologs, such that it is unclear what position the number "39" refers to. For example, does the term refer to any 39th nucleic acid in a sequence or any 39th codon so long as it is the 39th codon in a sequence, or to a nucleotide or codon position which could be the 39th codon in a sequence (but is not due to a truncation for example). The metes and bounds of the claim are therefore unclear.

Response to Arguments

5. The response asserts that claim 15 is clearly drawn to an isolated nucleic acid comprising the recited sequence and not to any nucleic acid polymorphic to the recited sequence. This argument has been thoroughly reviewed but was found unpersuasive because it is not clear which allele of the polymorphism the claim is limited to as noted above. Additionally, the claim now recites "comprising a phospholamban polymorphism" which encompasses more than a single polymorphism. If applicants are attempting to claim SEQ ID NO: 1 where position 116 is a G, the claim could be amended to recite: "An isolated nucleic acid molecule comprising SEQ ID NO: 1 where position 116 is a G" or "An isolated nucleic acid comprising SEQ ID NO: 7".

With regard to claim 19, the response asserts that the dependency of claim 19 from claim 15, thereby overcoming the lack of reference for the recited L39StopCodon mutation. This argument has been thoroughly reviewed but was not found persuasive as the metes and bounds of claim 15 remain unclear for the reasons set forth above. Additionally, it is still unclear, especially in the context of nucleic acids which comprise polymorphic fragments of SEQ ID NO: 1, which continues to be encompassed by the claims, what number "39" refers to, for example, the 39th nucleotide of any sequence, the 39th codon? Claim 15 is limited to a nucleic acid molecule, not a protein. It is noted that should claim 15 be amended as suggested above, claim 19 would no longer further limit it.

The rejections are therefore maintained

6. Claims 15, 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 15 as amended to recite "nucleic acid comprising a phospholamban polymorphism comprising", continues to encompass any nucleic acid comprising a portion of SEQ ID NO: 1, but which is polymorphic at any position, or polymorphic on either side of SEQ ID NO: 1, as well as any fragments of such polymorphic SEQ ID NO: 1 from any source (It is noted that a T already exists at position 116 of SEQ ID NO: 1). The claims therefore encompass an extremely large genus of nucleic acid variants, homologs, and mutants of SEQ ID NO: 1, from any source.

The specification, however, has only described a single polymorphism within SEQ ID NO: 1, T to G at position 116, which is associated with dilated cardiomyopathy (DCM) when present as a homozygous mutation (see pages 10-11 and 16 of the specification; now SEQ ID NO: 7). SEQ ID NO: 7 appears to encode the full length 52 amino acid human phospholamban protein with a mutation at position 116 which replaces the T in SEQ ID NO: 1 to a G. The claimed recitation, however, encompasses a large genus of nucleic acids which comprise polymorphisms at any position of SEQ ID NO: 1 or anywhere in genomic sequences on either side of SEQ ID NO: 1. The genus includes an enormous number of polymorphisms for which no written description is provided in the specification.

With regard to claims 18 and 19, which depend from claim 15, the specification provides no description of any other mutations which result in deletion of a cleavage site in humans, nor any such polymorphisms in any other species or ones that would result in a stop codon at a position designated as "39". Other than providing the sequence of SEQ ID NO: 1 and defining the T to G mutation at position 116, the specification does not describe the attributes needed for a nucleic acid to be generally identified as "a phospholamban polymorphism". With regard to claim 19, the only mutation in humans supported by the specification is a T to G mutation at position 116 of SEQ ID NO: 1, and the only other mutation described is in the rabbit phospholamban protein which results in a L39X mutation. However, without a reference for the number "39", it is not clear what position "39" the claim refers to. The claim broadly encompasses any nucleic acid which would encode a stop codon at position "39" of any phospholamban mutant, variant, or homolog sequence from any source.

This large genus is represented in the specification by only the particularly named polymorphism for which data is provided demonstrating an association in homozygous form with DCM. Thus, applicant has express possession of only 1 particular polymorphism, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed which would permit selection of sequences as polymorphisms. No written description of alleles, of upstream or downstream regions containing additional sequence, which are mutated or associated with DCM are described in the specification. The single T to C polymorphism at position 116 within SEQ ID NO: 1 is not representative of the large genus of mutants and variants of SEQ ID NO: 1 or homologs of SEQ ID NO: 1 from any source. For example, Schmitt (Schmitt et al; Science, vol. 299, pages 1410-1413; 2003) teaches a C to T mutation at position 25 leading to an Arg to Cys mutation at amino acid 9, of human phospholamban. The instant specification provides no description or guidance as to the existence of this polymorphism. The instantly disclosed polymorphism leading to a stop codon at amino acid 39 does not appear to be representative of the polymorphism at position 9 taught by Schmitt because the polymorphism taught by Schmitt appears to be disease associated in the heterozygous state whereas the instantly disclosed polymorphism at position 116 only appears associated in the homozygous state (specification at page 16 teaches that individuals in the heterozygous state did not show any detectable clinical phenotype). Secondly, the instantly disclosed polymorphism results in a mutation in the transmembrane domain of phospholamban, whereas the mutation disclosed by Schmitt is in domain Ia. The teachings of the specification provide no way to predict the existence or affect of the polymorphism taught by Schmitt.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids and polymorphisms in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the genus of nucleic acids and polymorphisms encompassed by the broadly claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acids and polymorphisms, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai

Pharmaceutical Co. Ltd., 18 USPQ2d 1016. The current situation is a definition of the compound solely based on its functional utility, as a polymorphism, without any definition of the particular polymorphisms claimed.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to Arguments

7. The response traverses the rejection and states that "the recitation makes it clear that Applicants are claiming an isolated nucleic acid, and that the nucleic acid comprises a polymorphism of phospholamban and that the nucleic acid comprises the particular mutation of sequence as set forth in SEQ ID NO: 1". This argument has been thoroughly reviewed but was found unpersuasive for the reasons noted above. Given that a T already exists at position 116 of SEQ ID NO: 1, it is not clear if the claim is limited to a T or a G at that position. Further, the recitation of "comprising a phospholamban polymorphism comprising" encompasses more than a single polymorphism. The examiner notes the assertion that "Applicants do not intend to claim the genus having the scope described by the examiner". It is suggested that claim be amended to

recite "An isolated nucleic acid molecule comprising SEQ ID NO: 1 where position 116 is a G" or "An isolated nucleic acid comprising SEQ ID NO: 7". It is noted that should this amendment be made, claims 18, 19, and 21 would not further limit it.

The rejection is therefore maintained.

Claim Rejections - 35 USC § 102

8. Claims 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession number X15075 (September 1993) as evidenced by New England Biolabs, 1995 catalog, page 13.

Accession number X15075 teaches the mRNA for pig phospholamban which is polymorphic with respect to SEQ ID NO: 1 at 10 positions (10 mismatches -see alignment). The claim recites "nucleic acid comprising a phospholamban polymorphism comprising" and therefore encompasses a nucleic acid molecule which "comprises" a phospholamban polymorphism. The recitation of "comprising" preceding the recitation of " a phospholamban polymorphism" encompasses more than one polymorphism. Further, the term "polymorphism" is normally used to denote a nucleotide change, therefore, a nucleic acid which comprises a "phospholamban polymorphism" only limits the claim to any nucleic acid which has a G or a T as this is a "phospholamban polymorphism" and it is the specific polymorphism found at position 116 of SEQ ID NO: 1.

Accordingly, the claim has been broadly interpreted to encompass a nucleic acid that has polymorphisms or mutations with respect to SEQ ID NO: 1. With regard to claim 18, the recitation of "comprising a mutation that results in deletion of a cleavage site for restriction

endonuclease" has been given no patentable weight as the method of obtaining the nucleic acid, that is mutating it, does not distinguish from a nucleic acid itself. A nucleic acid molecule is defined by its sequence, not by the fact that it was obtained by mutation. Accordingly, Accession number X15075 contains a number of sequences which could comprise a cleavage site for a restriction enzyme but do not. For example, X15075 comprises the sequence of "ACCT" (positions: 253-256), which is not recognized by AluI, which normally cleaves at "AG/CT". Thus the recitation of "comprising a mutation that results in deletion of a cleavage site for a restriction endonuclease" does not distinguish the claimed molecule from that of Accession number X15075. [It is noted that the sequence of X15075 is specifically polymorphic at the position which corresponds to position 81 of SEQ ID NO: 1 or 7 (see alignment). The human sequence comprises the polynucleotide AGCT, whereas the sequence of X15075 comprises "ACCT"].

9. Claims 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession number M60411 (Jan 1995).

With regard to claim 15, as noted above, the recitation of "nucleic acid comprising... G to T... at position 116... as set forth as SEQ ID NO:1" encompasses a molecule which comprises SEQ ID NO: 1. Accession number M60411 teaches the sequence of human phospholamban which completely comprises SEQ ID NO: 1 where T is located at the position corresponding to position 116 of SEQ ID NO: 1. With regard to claim 18, the recitation of "comprising a mutation that results in deletion of a cleavage site for restriction endonuclease" has been given no patentable weight as the method of constructing the nucleic acid, that is mutating it, does not

distinguish from a nucleic acid itself. A nucleic acid molecule is defined by its sequence, not by the fact that it was obtained by mutation. Accordingly, Accession number M60411 contains a number of sequences which could comprise a cleavage site for a restriction enzyme but do not. Thus the recitation of "comprising a mutation that results in deletion of a cleavage site for a restriction endonuclease" does not distinguish the claimed molecule from that of Accession number M60411.

Response to Arguments

10. The response asserts that none of the 10 mutations occurring in the X15075 reference comprises the T to G mutation at position 116 of SEQ ID NO: 1. This argument has been thoroughly reviewed but was not found persuasive as the claim does not appear to require, in any sequence, a G which corresponds to position 116 of SEQ ID NO: 1. Arguments made with regard to M60411 have been thoroughly reviewed but are not persuasive for the reasons made of record above. The rejections are therefore maintained.

11. Claims 15 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Kimura (Kimura et al; Mol. Pharmacol, vol. 61, pages 667-673, 2002).

Kimura teaches constructing S16D and T17D mutants of human phospholamban DNA (see col. 2, page 668 "Oligonucleotide directed mutagenesis) from a fragment of the DNA encoding human phospholamban: Met-1 to Gln-26. The claim has been broadly interpreted to encompass a nucleic acid which is a fragment of SEQ ID NO: 1 and which has polymorphisms with respect to SEQ ID NO: 1. Further, the term "polymorphism" is normally used to denote a

nucleotide change, therefore, a nucleic acid which comprises a "phospholamban polymorphism" only limits the claim to any nucleic acid which has a G or a T as this is a "phospholamban polymorphism" and it is the specific polymorphism found at position 116 of SEQ ID NO: 1.

With regard to claim 18, the recitation of "comprising a mutation that results in deletion of a cleavage site for restriction endonuclease" has been given no patentable weight as the method of constructing the nucleic acid, that is mutating it, does not distinguish from a nucleic acid itself. A nucleic acid molecule is defined by its sequence, not by the fact that it was obtained by mutation. Accordingly, Kimura teaches nucleic acid molecules which could comprise a cleavage site for a restriction enzyme but do not. Thus the recitation of "comprising a mutation that results in deletion of a cleavage site for a restriction endonuclease" does not distinguish the claimed molecule from those taught by Kimura.

Response to Arguments

12. The response traverses the rejection and asserts that "Applicants admit to being puzzled as to why the Examiner appears focused on the length of the inventive sequences, yet ignores the defining limitation, that is the presence of a mutation at a defined position, that position having a reference with respect to wildtype phospholamban. The instant claims encompass polymorphisms of phospholamban defined by the presence of a particular mutation". This argument has been thoroughly reviewed but was not found persuasive as no teaching that a specific position is polymorphic is needed to anticipate the presence of a particular nucleotide allele. Further, given that the claims continue to encompass nucleic acids which comprise any size fragments of SEQ ID NO: 1, which can include any sequences on either side, not limited to

those of SEQ ID NO: 1, and further wherein such nucleic acid is polymorphic with regard to SEQ ID NO: 1, the recitation of position "116" is arbitrary. The claim is not limited to a nucleic acid which is at least 116 nucleotides long. The rejection is therefore maintained

13. Claims 15, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796).

Claim 15 encompasses fragments of the recited SEQ ID NO:, which has no defined length. Claims 18 and 19 specifically encompass fragments with no defined length. Brennan teaches every permutation of trimer nucleic acid molecules, as well as specifically "TGA" (see Figure 1A) which encodes a stop codon (claim 19). Further, Brennan teaches making every possible 10 mer nucleic acid. Accordingly, the teachings of Brennan anticipate the broad genus of nucleic acids encompassed by the claims.

14. Claims 15, 18, and 19 are rejected under 35 U.S.C. 102(a) and 103(e) as being anticipated by Fodor et al (US Pregrant Publication 2001/00453519).

Claim 15 encompasses fragments of the recited SEQ ID NO:, which has no defined length. Claims 18 and 19 specifically encompass fragments with no defined length. Fodor teaches making every possible 10 mer nucleic acid (see example 2). Accordingly, the teachings of Fodor anticipate the broad genus of nucleic acids encompassed by the claims.

Conclusion

15. No claim is allowed.

16. Claim is objected to for being dependent on a rejected claim and would be allowable if rewritten in independent form to recite "An isolated nucleic acid molecule comprising the sequence of SEQ ID NO: 1" or "an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth as SEQ ID NO:1", which are identical in scope.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jehanne Sitton
Primary Examiner
Art Unit 1634

Jehanne Sitton
12/7/06